

Attorney Docket No.: **DEX-0142**  
Inventors: **Macina et al.**  
Serial No.: **09/802,674**  
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levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in the patient ~~versus~~ the normal human control is associated with a cancer which is progressing in stage and an increase is associated with a cancer which is regressing in stage or in remission.

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**REMARKS**

Claims 1-10 are pending in the instant application. Claims 6 and 8-10 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 1-5 and 7 have been rejected. Claims 1-5 have been amended and claim 7 has been canceled in light of the amendments to claims 1-5. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

**I. Finality of Restriction Requirement**

The Examiner has made final the Restriction Requirement mailed May 6, 2002. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled non-elected claims 6 and 8-10, without prejudice. However, in light of the finality of the Restriction Requirement, Applicants

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reserve the right to file a divisional application to the canceled subject matter.

## **II. Information Disclosure Statement**

The Examiner has indicated that references AD, AE, AQ, AR, AS and AU of the Information Disclosure Statement were not found in the instant application. As stated in the transmittal sheet forwarded with the IDS, these references were not provided with the Information Disclosure Statement as they are standard reference texts cited in the application for their teachings of general procedures known to those of skill in the art. It is Applicants' belief that the United States Patent Office has access to these standard reference texts and due to the voluminous nature, copies are not being provided. Further, these general teachings of procedures do not affect the novelty or unobviousness of the instant claimed invention.

## **III. Rejection of Claims 1-5 and 7 under 35 U.S.C. § 112, first paragraph**

Claims 1-5 and 7 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most

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nearly connected, to make and/or use the invention. Specifically, the Examiner suggests that there is no nexus between the GSG identified as SEQ ID NO:3 and the GSGs, Cln114 and Cln115 for which data is presented in the specification. Further, the Examiner suggests that Applicants have not provided any disclosure enabling the use of variant and degenerate polynucleotides of SEQ ID NO:3. In addition, the Examiner suggests that Applicants have not set forth any supporting evidence that suggests that SEQ ID NO:3 is a unique tumor or molecular marker for gastrointestinal cancer.

Applicants respectfully traverse this rejection.

In Figure 3 of U.S. Provisional Application No. 60/188,061, filed March 9, 2000, from which the instant application claims priority, the nucleic acid sequence of Cln115 (SEQ ID NO:3) is disclosed. A courtesy copy of the Figures from the as-filed provisional application is provided herewith.

Figure 3 from the priority application establishes the nexus between Cln115 and SEQ ID NO:3.

Further, at page 4 of the Office Action, the Examiner acknowledges that the evidence presented in the specification suggests that with the occurrence of Cln114 and Cln115 underexpression in colon cancer, this can be interpreted as

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diagnostic of gastrointestinal cancer. Thus, since the nexus between Cln115 and SEQ ID NO:3 has now been established, this evidence in the specification must also be indicative of SEQ ID NO:3 being a unique tumor or molecular marker for gastrointestinal cancer.

In addition, and without conceding the correctness of the Examiner's position, Applicants have amended the claims to exclude the use of variant and degenerate polynucleotides of SEQ ID NO:3.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested in light of these amendments.

**IV. Rejection of Claims 1-5 and 7 under 35 U.S.C. § 112, second paragraph**

Claims 1-5 and 7 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that claims 1-5 and 7 are vague and indefinite in the recitation of "GSG". The Examiner also suggests that the claims 1-5 are vague and indefinite in the recitation of "determining GSG

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levels" because it is not clear what type of GSG molecule is measured. Claim 7 is also suggested to be indefinite in the recitation of non-elected subject matter, namely reference to claim 6 and SEQ ID NO:1.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claims 1-5 to delete the term GSG and clarify that the molecule determined comprises SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3. Support for this amendment is provided in the specification at pages 4-5. Claim 7 has been canceled in light of amendments to claims 1-5.

Withdrawal of these rejections under 35 U.S.C. § 112, second paragraph, is therefore respectfully requested.

**V. Rejection of Claims 1-5 and 7 under 35 U.S.C. § 101**

Claims 1-5 and 7 have been rejected under 35 U.S.C. § 101 as not being supported by either a specific, substantial, credible or asserted utility or a well established utility.

Applicants respectfully traverse this rejection.

As discussed in Section III, *supra*, evidence establishing the nexus between SEQ ID NO:3 and Cln115 was set forth in the provisional application from which the instant application claims

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priority. A courtesy copy of Figure 3 from U.S. provisional application serial No. 60/188,061 with the nucleic acid sequence of Cln115 (SEQ ID NO: 3) is provided herewith. Further, the claims have been amended and are now drawn to determination of levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3. Claim 7 has been canceled in light of the amendments to claims 1-5.

As also discussed in Section III, *supra*, the specification has been acknowledged by the Examiner to provide evidence of the usefulness of Cln115, and thus SEQ ID NO:3, as a tumor diagnostic marker.

Accordingly, the claims as amended are clearly supported by a specific, substantial, credible utility.

Withdrawal of this rejection is therefore respectfully requested.

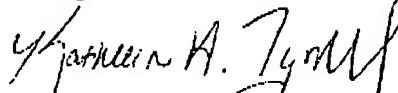
#### **VI. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

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Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please cancel claims 6-10 without prejudice.

Please amend the claims as follows:

1. (amended) A method for diagnosing the presence of gastrointestinal cancer in a patient comprising:
  - (a) determining levels of ~~ESG SEO ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEO ID NO: 3~~ in cells, tissues or bodily fluids in a patient; and
  - (b) comparing the determined levels of ~~ESG SEO ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEO ID NO: 3 with levels of ESG SEO ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEO ID NO: 3~~ in cells, tissues or bodily fluids from a normal human control, wherein a change in determined levels of ~~ESG SEO ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEO ID NO: 3~~ in said patient versus normal human control is associated with the presence of gastrointestinal cancer.
2. (amended) A method of diagnosing metastases of

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gastrointestinal cancer in a patient comprising:

- (a) identifying a patient having gastrointestinal cancer that is not known to have metastasized;
- (b) determining GGG levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in a sample of cells, tissues, or bodily fluid from said patient; and
- (c) comparing the determined GGG levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 with levels of GGG SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in cells, tissue, or bodily fluid of a normal human control, wherein a decrease in determined GGG levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in the patient versus the normal human control is associated with a cancer which has metastasized.

3. (amended) A method of staging gastrointestinal cancer in a patient having gastrointestinal cancer comprising:

- (a) identifying a patient having gastrointestinal cancer;
- (b) determining GGG levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the

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antisense sequence of SEQ ID NO: 3 in a sample of cells, tissue, or bodily fluid from said patient; and

(c) comparing determined GGG levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 with levels of GGG SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in cells, tissues, or bodily fluid of a normal human control, wherein a decrease in determined GGG levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in said patient versus the normal human control is associated with a cancer which is progressing and an increase in the determined GGG levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 is associated with a cancer which is regressing or in remission.

4. (amended) A method of monitoring gastrointestinal cancer in a patient for the onset of metastasis comprising:

(a) identifying a patient having gastrointestinal cancer that is not known to have metastasized;

(b) periodically determining levels of GGG SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the

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antisense sequence of SEQ ID NO: 3 in samples of cells, tissues, or bodily fluid from said patient; and

(c) comparing the periodically determined ESS levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 with levels of ESS SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in cells, tissues, or bodily fluid of a normal human control, wherein a decrease in any one of the periodically determined ESS levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in the patient versus the normal human control is associated with a cancer which has metastasized.

5. (amended). A method of monitoring a change in stage of gastrointestinal cancer in a patient comprising:

(a) identifying a patient having gastrointestinal cancer;  
(b) periodically determining levels of ESS SEQ ID NO:3 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 3 in cells, tissues, or bodily fluid from said patient; and  
(c) comparing the periodically determined ESS levels of SEQ ID NO:3 or a polynucleotide which hybridizes under stringent

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conditions to the antisense sequence of SEQ ID NO: 3 with levels of SEQ ID NO:3 or a polynucleotide which hybridizes under  
stringent conditions to the antisense sequence of SEQ ID NO: 3 in  
cells, tissues, or bodily fluid of a normal human control,  
wherein a decrease in any one of the periodically determined ~~696~~  
levels of SEQ ID NO:3 or a polynucleotide which hybridizes under  
stringent conditions to the antisense sequence of SEQ ID NO: 3 in  
the patient versus the normal human control is associated with a  
cancer which is progressing in stage and an increase is  
associated with a cancer which is regressing in stage or in  
remission.

**Figure 1: Nucleic Acid Sequence of Cln114 (SEQ ID NO:1)**

ACTCCCCCTCCGAGGGTCTGACCACGCTGGGCCAGTCATACGCCACGCGTCCGGGAC  
 CTCCTGCCCTCAGGTGATCCATCCACCTCGGCCAGTCAAAGTGTGGGATTACAGGCATGA  
 GCCATTGCAcccAGCCGATACTACTATATCCCCATTTCAGATGAGCAGTCAGGCAAATTG  
 AGGGTAAGGCATGACCCATGATCATACAGCTGAGAAGTGGCAAAGGCAGGATTGAACC  
 TAGAACCTCTGGCTCCACACACTAGTAATCTAAACCACTCTCCCTACAATACAACATACG  
 TCGTAAAGATGTGTGGGGCACGCAATCAACGTAGGTCCCTCACAGTTGCTGGGAGAG  
 GCAGGAATTGCAAGTTCCTCCGCTTCTCCCTCCGCTGCCACCTGTCCCTGGGTCAATT  
 CCTGCAGCCTGCCCTGCCCTGCCCTGGTCTCACCCCTCCCTGCCAACAGAACAGTCTGGGCA  
 GGGTTTATGGGCTCTGATAAGGCCCTGGCAGGGCGAAGTTCATGAGCACTTCTCTT  
 GCAGGAGGGCGTAGGGGAGGGGACCCAGGTGATTGGGTCTGGCTGGTCAACCAGCGAAG  
 CTGGCAAGGGAAGGGAGACTAGGGTGCCTCTAGGACAAGCCGACAGCCTGAGAGTCCCAGAA  
 GAGGAGGCCCTGTTGGACCTCCCCCTGCCAGCCACTCCCTACCCCTGGGTATAAGAGCCACC  
 ACCGCCTGCCATCCGCCACCATCTCCACTCTGCAGCTCTCACAGGACCAGCCACT  
 ACCCCACCTCGAGCGATGGCCTATGTCCCCGACCCGGCTACCGCCACCTACAACCC  
 CACGCTGCCTTACTACCAGCCATCCCCGGCGGGCTCAACGTGGGAATGTCTGTTACAT  
 CCAAGGAGTGGCCAGCGAGCACATGAAGCGGTTCTCGTGAACTTTGTGGGTGGCAGGA  
 TCCGGGCTCAGACGTCGCCCTCCACTTCAATCCGGGTTTGACGGCTGGACAAAGGTGGT  
 CTTCAACACGTTGCAGGGCGGAAGTGGGGCAGCGAGGAGAGGAAGAGGAGCATGCCCT  
 CAAAAAGGGTGCCGCTTTCAGCTGGTCTTCATAGTCCCTGGTCTGAGCACTACAAGGTGGT  
 GCTAAATGAAATCCCTCTATGAGTACGGCACCGGCTCCCTACAGATGGTCACCCA  
 CCTGCAAGTGGATGGGATCTGCAACTTCAATCAACTTCACTCGGAGGCCAGCCCT  
 CGGCCAGGGACCCCGATGATGCCACCTTACCCCTGGTCCGGACATTGCCATCAACA  
 GCTGAACAGCCCTGCCACCATGGAAGGACCCCAACCTCAACCCGCTGTGCCATATT  
 CGGGAGGCTGCAAGGAGGGCTCACAGCTCGAAGAACCATCATCAAGGGCTATGTGCC  
 TCCCACAGGCAAGAGCTTGCCTATCAACTCAAGGTGGCTCTCAGGGGACATAGCTCT  
 GCACATTAATCCCCGATGCCAACGGTACCGTGGTCCGGAACAGCCTCTGAATGGCTC  
 GTGGGGATCCGAGGAGAGAAGATCACCCACAAACCATTGCTCCGGACAGTTCTTGA  
 TCTGTTCCATTGCTGTGGCTGGATCGCTCAACGTTACGCCAATGGCCAGCACCTCT  
 TGACTTGGCCATGCCCTCTGGCTTCCAGAGGGTGGACACATTGAAATCCAGGCTGA  
 TGTCACCTGTCCTATGTCAGATCTAATCTATTCTGGGGCCATAACTCATGGAAAAC  
 AGAATTATCCCCTAGGACTCCCTCTAAGCCCTAATAAAATGTCTGAGGGTCTCATG

**Figure 2: Amino Acid Sequence (SEQ ID NO:2) encoded by Cln114**

MAYVPAPGYQPTYNPLPYQPIPGGLNVGMSVYIQQVASEHMKRFFVNFGVQDPGSDV  
 AFHFNPFRDGWDKVVFNTLQGGKGSEERKRSMPFKKGAAFLVFIVLAEHYKVVVNGNP  
 FYEYGHRLPLQMVTHLQVDGDLQLQSINFIGGQPLRPQGPPMMPPYPGPGHCHQQLNSLP  
 TMEGPPTFNPPVPYFGRLQGGLTARRTIIKGYVPTGKSFAINFKVGSQGDIALHINPR  
 MGNGTVVRNSLLNGSWGSEEKKITMNPFGPGQFFDLSIRCGLDRFKVYANGQHLFDFAHR  
 LSAFQRVDTLEIQGDVTLSYVQI

**Figure 3: Nucleic Acid Sequence of Cln115 (SEQ ID NO:3)**

CTTTAGCCAAACAGTAAAAATAATTGATGCTACCCCTACAAATGTCCAAACTCTAGTAT  
 ATCATATTCTAAGTTACAGCAAATATTAGTCCTGCTAAACCCAGGGAGCTTGGCAAAA  
 TGTTTTTGACAGTAAATTGCTCTGATTATATTAACCTAGTCAAAGAGGTGTTGTA  
 ACATATTAGAGCTTGTAGGTGGGTTAACACCACCAATCAAGAGGTCAATTCTAA

CAGAAAGCCTGGATCAGAAAACCATCACCCCTAAAAAACATGCCTTACATATTAACACA  
 CTCTGAAATCCAGTCAAAATATGACTAAAGGCCCTGCCATGACTGATGTATTCTCCTGG  
 CCAACGCCAAACAAATGGGAGGCCCTGGTTACGAGTCAGCCTCAGGGACTTGTACATTT  
 TACTTGGTTCTTCTTGTATTGTCTATAAATGTTCTATGCTGTTAGTGAAC  
 TTAGGCCCTATTCTGTAGAAGTCTCCTCTACTATTAGGCCACTCAAACACCCCAAATAA  
 TTGAGTTCAAAATCGACATCAAGATATAAAGGAATCAGTGAACAAATATATTTCATATAT  
 GGTATTTTATTGATTAATGTGCTGTCTTGACCTAGTATGGAGGCCCTGGCTAGAGGCTG  
 GTCAGTTCTCTTGTAGCAGCTGATTAATCCACACCCAAACACTTCCCTATCAGG  
 TTCTCACACTCTGGGGCACTATGTACCCACTCTAACACACAGGGCAGACATCAGAC  
 AATTAAGGACAGGCCCATGCCCAAAGCCGCAAACATTATGCAAATTATTCAAATAA  
 TTCAACCTAGCTAACCCACCCCTTTGCTGTACATAAGCTGCCCATCCCCCTCAGCC  
 TGTGGTACCCAGTCCTCAGGTGCAACCCCTGCGTGGCTCTGTGGCAGCCTCTCTCA  
 TTCAGAGCTGTTCCACAGAGGTAGTGAAAAGAACTGGATTTCAGTTCAAGTTCACTTGCAA  
 GAGAAAAAGAAAACCTAGTAGAAGATAATGGCAAGTCCAGACTGGGATATGATGACAAA  
 AATGGCCTGAAACAATGGAGCAAGCTGTATCCCATTGCCAATGGAATAACCAATCCCCT  
 GTTGATATTAAAACCAGTCACAAACATGACACCTCTGTAAACCTATTAGTGTCTCC  
 TACAACCCAGCCACAGCCAAAGAAATTATCAATGTGGGCATTCTTCCATGTAATT  
 GAGGACAACGATAACCGATCAGTGTGAAAGGTGGCCTTCTCTGACAGCTACAGGCTC  
 TTTCAGTTCACTGGGAGCTCACGTAGCTCAGTGGAAATTCTGCAAAGTACTCCAGC  
 GGAGTCAAATATTCTGCCAGCTCACGTAGCTCAGTGGAAATTCTGCAAAGTACTCCAGC  
 CTTGCTGAAGCTGCCTCAAAGGCTGATCGTTGGCAGTTATTGGTGTGTTGATGAAAGGTT  
 GGTGAGGCCAACCCAAACCTGCAGAAAAGTACTTCATGCCCTCCAAGCAATTAAAACCAAG  
 GGCAAAACGAGCCCATTCAAAATTGACCCCTCTACTCTCCTTCCATCCCTGGAT  
 TTCTGGACCTACCCCTGGCTCTGACTCATCCTCTCTTTATGAGAGTGTAACTTGGATC  
 ATCTGTAAGGAGAGCATCAGTGTAGCTCAGCTCAGAGCAGCTGGCACAATTCCGAGCCTTCTA  
 TCAAATGTTGAAGGTGATAACGCTGTCCCCATGCAGCACAACACGCCAACCCAAACCT  
 CTGAAGGGCAGAACAGTGGAGAGCTCATTGATGATTCTGAGAAGAAACTTGTCCCTCC  
 TCAAGAACACAGCCCTGCTCTGACATAATCCACTAAAATAAATTGAAAGAAATAA  
 ATTATTCAATATTAGCAAGACAGCATGCCCTCAAATCAATCTGTAACAACTAAGAAACT  
 TAAATTAGTCTTACTGCTTAATTCAAATAAATTAGTAAAGCTAGCAAATAGTAATC  
 TGTAAGCATAAGCTTATCTTAAATTCAAGTTACTTGAGGAAATTCTTAAAATTACAAC  
 TAAGTGTATTGATGTCTATTGAGCTTATTGAAACCAATAAAATAATTGAAAGAAATAA  
 TTTCTTCTGTTGTGCACTGTTCTAAACCATTAAGTTCTACTCCATTACATTCA  
 AAAATCTTAAATACTTACTTGCAAGAGTATTGCTTCAATAACACACCTAACAGAGCA  
 GCTGGAGATGAAATATTGGAAATTGCTTACTCCTGAAGACAAAAATATAGCTGA  
 GATGACCAACTGGATTAAATCGTTATGCTGGCCACACATTGCTACCATTTGTGTTGTCT  
 GTGATCAAATGATTATCTTTATATAGGAAGATGACGCTCTGGATAATTGCTTCACTT  
 CTTCTCCCCACGTTAGCAAGGACAATGCTCTGCCATTATTACAACTAGTTAGTTGC  
 ATGGAGAATCTTACTTTAAAATTGGAAGAAAAGTCACAAGTGAATGGTTATAAAAATG  
 CTAAAGAAGTCATTCTGCTTAGAATCATATAGAAACATCATGCAATTCTTTAGTCAGAT  
 GTGCGCTTCACCTTATGCTATTGACACACAATAATTGTACATGTTA  
 TGGACTATAGTGTGGTGTGTTCTGTTGTTGAGACAAGGTCTCACTCT  
 GCCAGTCAGGGTGGAGTGCATGGT

Figure 4: Amino Acid Sequence (SEQ ID NO:4) encoded by Cln115

MASPDWGYDDKNGPEQWSKLYPIANGNNQSPVD (KTSETKHDTSLKPI SVSYNPATAKEI  
 INVGHSFHVNFDNDNRSLVKGGPFSDSYRLFQFHFHWGSTNEHGSEHTVDGVKYSaelh  
 VAHWNSAKYSSLAEEASKADGLAVIGVLMKVGLEANPKLQKVLDALQAIKTKGKRAPFTNF  
 DPSTLLPSSLDFTWYPCSLTHPPLYESVTWIIKESISVSSEQLAQFRSLLSNVEGDN  
 PMQHNNRPTQPLKGRTVRASF